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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/078,225 | 02/19/2002 | James A. Hendrix | A-4015 US NP | 6185 |

5487 7590 05/16/2003

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EXAMINER

PATEL, SUDHAKER B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1624

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,225

Applicant(s)

James A. Hendrix et al

Examiner

SUDHAKER PATEL, D.Sc.Tech.

Art Unit

1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 12, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-90 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims in part)1-22,24,25,27,28,40,42,43-90, drawn to compounds, composition, a method of use and the first recited process of making for Formula (I)wherein component A = CH; n = 1, Y = 0, making a 6-membered saturated monocyclic ring/piperidine, classified in class 546, subclass 184 and many more depending on the values of R1, R3, and the bridge $[-B-CO]-NR_2-R_1$, class 514, subclass 315 and many more depending on values of R, R1-R3,B and integer g. *If this group is elected a single specific species from working example must be disclosed with all variables exactly defined.* Additionally, further restriction will be required as there are many meanings of variables, and the same will provide multiples of species with different structures e.g.
 - the R variable has many possibilities consisting of (a)-(w);
 - the group $[-B-CO]-$ has (a)-(f) variations;
 - R2 group has (a)-(jj) variations and R85 which is (q) alternative for variable R2 has additional possibilities (a)-(k);
 - NR1R2 group can be either open ended or closed ended to form a ring with N, and there are more than 34 variations .

Art Unit: 1624

- II. Claims(in part) 1-17,45,46-90, drawn to compounds, composition, a method of use and the first recited process of making for Formula (I)wherein component A = CH, n = 1, Y = 2 making a bicyclic ring of 7:4-combination/monoaza-bicyclic/pyrrolido-cyclo-heptane, classified in class 548, subclass 452 and many more depending on the meaning of the variables R, R1-R3, B and integer g, class 514, subclass 412 and many more depending on the meanings of variables R, R1-R3, B. *If this group is elected a single specific species from working example must be disclosed with all variables exactly defined.* Additionally, further restriction will be required as there are many meanings of variables, and the same will provide multiples of species with different structures as stated in Group I. above.
- III. Claims(in part)1-17,23,26,29-39,41,45-90, drawn to compounds, composition, a method of use and the first recited process of making for Formula (I)wherein component A = N, n = 1, Y = 0 forming a saturated 6-membered ring with 2N/piperazine, classified in class 544, subclass 358 and many more depending on the meanings of variables R, R1-R3, B and integer g, class 514 subclass 412 and many more depending on the meanings of variables R, R1-R3, B. *If this group is elected a single specific species from working example must be disclosed with all variables exactly defined.* Additionally, further restriction will be required as there

Art Unit: 1624

are many meanings of variables, and the same will provide multiples of species with different structures as stated in Group I. above.

- IV. Claims(in part) 1-7,45,46-90, drawn to compounds, composition, a method of use and the first recited process of making for Formula (I)wherein component A = N, $n = 1$, $Y = 2$ forming saturated Diaza-bicyclo ring having 7:5-fusion, classified in class 540 , subclass 500 and many more depending on the meanings of variables R, R1-R3, B and integer g, class 514 subclass 221 and many more depending on the meanings of variables R, R1-R3, B.
- V.. Claims(in part) 1-17,45-90, drawn to compounds, composition, a method of use and the first recited process of making for Formula (I)wherein component A = CH, $n = 2$, $Y = 0$ forming a saturated mono-aza-monocyclic 7 membered ring , classified in class 540 , subclass 484 and many more depending on the meanings of variables R, R1-R3, B and integer g, class 514 subclass 212.01 and many more depending on the meanings of variables R, R1-R3, B. *If this group is elected a single specific species from working example must be disclosed with all variables exactly defined.* Additionally, further restriction will be required as there are many meanings of variables, and the same will provide multiples of species with different structures as stated in Group I. above.
- VI. Claims(in part) 1-17,45,46-90, drawn to compounds, composition, a method of use and the first recited process of making for Formula (I)wherein component A =

Art Unit: 1624

N, $n = 2$, $Y = 0$ forming a saturated 1,4-diaza-monocyclic ring, classified in class 540, subclass 575 and many more depending on the meanings of variables R, R1-R3, B and integer g, class 514 subclass 218 and many more depending on the meanings of variables R, R1-R3, B. *If this group is elected a single specific species from working example must be disclosed with all variables exactly defined.* Additionally, further restriction will be required as there are many meanings of variables, and the same will provide multiples of species with different structures as stated in Group I. above.

2. The inventions are distinct, each from the other because of the following reasons:

- The claims are drawn to structurally dissimilar compounds;
- The compounds are classified separately;
- The compounds require separate literature searches;
- The compounds are not art recognized equivalents, and
- They are made and used independently.

Additionally, the scope that a prior art anticipating one compound under 35 U.S.C. 102 would not render obvious another compound of the same claim under 35 U.S.C. 103.

Art Unit: 1624

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claims 1,45,46, 50, 59 are generic to a plurality of disclosed patentably distinct species comprising various combination of basic cores as recited in above I-VI groups. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from working examples with all variables exactly defined, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. A telephone call was made to Ms Kurys on 5/12/03 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1624

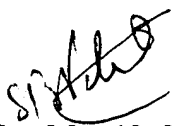
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc. Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.


S.p. May 13, 2003.


MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1600